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NOTICE OF EXCEPTION

Digital Mammography Machines with Tungsten Tube Targets

The Department of Community Health hereby grants an exception from rule R325.5638(2) for digital mammography machines with tungsten tube targets. R325.5638(2) requires that mammography machines shall be capable of an output at 28 kilovolts of not less than 500 milliroentgens per second at breast entrance for a 4.5-centimeter compressed breast with the compression plate in the beam for any mammographic technique that is used other than for magnification techniques. The intent of this rule was to prevent excessively long exposure times that could lead to retakes due to patient motion.

Image enhancement possible with digital technology can produce good quality images with higher energy x-ray spectra than is used with film imaging systems. The higher energy spectra allow lower doses with shorter exposures times and manufacturers have chosen tungsten tubes to provide the higher energy spectra. Because of the filters necessary to optimize image quality and dose, and because tungsten is not an efficient material for x-ray production at kilovolts necessary for mammography, these machines may not be capable of producing 500 milliroentgens per second output.

Digital mammography machines with tungsten tube targets are new technology since the promulgation of rule R325.5638(2). Digital mammography machines with tungsten tube targets that can produce high quality images with exposure times and doses equivalent to, or lower than, film mammography machines do not result in an undue hazard to public health and safety or property and meet the intent of rule R325.5638(2). Therefore, the Department excepts these digital mammography machines with tungsten tube targets from this rule.

This exception is authorized under R325.5031 of the Michigan Administrative Code and is effective immediately.

Mike Dankert, Director
Bureau of Health Systems
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